

## REMARKS

Claims 68-92 are pending in the subject application. Claims 68, 74, 79, and 83 are amended. Claims 93-129 are added. Applicants submit that the amendments introduce no new matter, support therefore being found throughout the application and drawings as originally filed. Favorable reconsideration in light of the amendments are remarks which follow a respectfully requested.

### 1. 35 U.S.C. 102 Rejections

Claims 68-91 are rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,478,776 to Rosenman et al. (hereinafter "Rosenman").

Applicants respectfully traverse.

Applicants recite, in amended claim 68, an implantable drug delivery device comprising a non-linear shaped body member having at least two deviations from a linear and that has a shape other than a substantially C-configuration and that is implanted within a patient during use of the device to deliver a drug substance to the patient via the body member; and a cap element that abuts an incision through which the device is inserted to stabilize the device once implanted.

Amended claim 79 is similar, and recites an implantable drug delivery device comprising a coil-shaped body member that is implanted within a patient during use of the device to deliver a drug substance to the patient via the body member; and a cap element that abuts an incision through which the device is inserted to stabilize the device once implanted.

New claim 111 is similar, and recites an implantable ocular drug delivery device comprising a coil-shaped body member that is implanted within a patient eye during use of the device to deliver a drug substance to the patient eye; and a cap element that mates against the patient eye outer surface while the body member is inserted to the eye.

New claim 116 is similar, and recites an implantable ocular drug delivery device comprising a non-linear shaped body member having at least two deviations from a linear and that has a shape other than a substantially C-configuration and that is implanted within a patient eye during use of the device to deliver a drug substance to the patient eye via the body member; and a cap element that mates against the patient eye outer surface while the body member is inserted to the eye.

As set out by Applicant, the cap 8 (as shown in Figs. 1-3c, 5a-5b) is located at the proximal end 4 of the body member 2 to assist in stabilizing the device 1 once implanted, with the cap 8 abutting the incision. The rim or cap 8 is designed such that it remains outside the eye (or other implantation region) and, as such, the rim or cap 8 is sized so that it will not pass into the eye (or other implantation region) through the opening through which the device is inserted. (See page 11, lines 18-31; page 24, lines 1-2)

Rosenman, on the other hand, describes catheter systems for delivering drug delivery structures into the myocardium. As shown in Fig. 16, the drug delivery structure 12 is helical in shape and is implanted within the myocardium so that the proximal tip 38 of the structure 12 is at a depth below the endocardial surface 44. As specified by Rosenman, this placement is important because it allows the endocardium to heal over the small helical needle track wound created by turning the device into the tissue such that, eventually, the healing response within the myocardium will seal the drug delivery structure off from the circulating blood within the heart chamber (indicated at item 45). (See e.g. col. 10, line 62-col. 11, line 9; col. 14, line 62-col. 15, line 8).

Applicants respectfully submit that the catheter systems and drug delivery structures of Rosenman are specifically adapted for insertion into the myocardium and other tissues. Rosenman is not at all directed to the insertion of implants in the eye, which is very different from the myocardium and other tissues. In particular, the eye is filled with a substance called the vitreous, which is a viscous, transparent substance composed mainly of water and therefore fundamentally different than solid tissue such myocardium. Furthermore, in order to place the

body member of the device in contact with the vitreous, the body member is passed through scleral tissue. Scleral tissue is a soft, viscoelastic material that is also fundamentally different than myocardial tissue.

As such, implants and implantation methods must be specifically designed taking into consideration the unique anatomical and histological features of the eye, and in particular the vitreous and sclera. Rosenman's delivery structures and methods are neither designed for nor are they suitable for use within the eye.

The Office asserts that Rosenman describes and shows in Figs. 18-19 "a cap element 56 that is fully capable of mating against a patient eye outer surface while the body member is inserted into the eye due to its size, shape and ability to work in the environment." Applicants respectfully disagree.

Rosenman shows and describes in Figs. 18-19 another structure for a delivery catheter distal end and the mating portion of the drug delivery helix – the head 56. The delivery catheter has outwardly biased fingers 53 with inwardly facing detents 54 which interact with mating detent receiving ports 55 on the head 56 of the helix 12. The head 56 is, thus, designed as a mechanism by which the delivery structure 12 can be grasped by a delivery catheter. The head 56, however, is not provided or designed as a cap capable of mating against a patient eye outer surface while the body member is inserted into the eye or capable of abutting an incision through which the device is inserted to stabilize the device once implanted. As shown by Rosenman, the head 56 has a small cross-sectional diameter that is smaller than the cross sectional diameter of the helix. The head 56 further has a large height required to provide detent receiving ports 55 for receiving inwardly facing detents 54 of the delivery catheter. This combination of a small cross-sectional diameter with a large height would not provide a cap that is capable of abutting an incision through which the device is inserted to stabilize the device once implanted or that is suitable for mating against a patient eye outer surface while the body member is inserted into the eye. For example, if the Rosenman device was inserted in the eye with the head 56 protruding from the eye, the protrusion above the eye surface would be unacceptably high and large. The

head 56 shown and described by Rosenman would interfere with the eye's natural blink mechanism and would likely result in irritation and movement (rather than stabilization) of the implant upon contact with the eyelid (e.g. upon blinking or closing the eye).

Further, Rosenman does not teach or suggest a head 56 in the form of a cap that abuts an incision through which the device is inserted to stabilize the device once implanted. As set forth above, Applicants' cap is designed such that it remains outside the eye and, as such, the cap is sized so that it will not pass into the eye through the opening in the eye through which the device is inserted. On the other hand, Rosenman explicitly provides a drug delivery structure that is inserted into the myocardium such that the proximal tip (i.e. head 56) of the structure is below the endocardial surface (i.e. the structure is completely embedded within the myocardial tissue). This allows the endocardium to heal over the helical needle track tissue such that the drug delivery structure is sealed off from the circulating blood within the heart chamber. Providing a head 56 in the form of a cap as taught by Applicants' would render the device of Rosenman "unsuitable for its intended purpose" and would result in "a change in the basic principle under which [Rosenman] was designed to operate" (see MPEP 2143.01). In particular, Rosenman provides a myocardial implant that is designed for implantation within the myocardium with the proximal end below the endocardial surface so that the endocardium heals over the incision and seals off the implant. Providing Rosenman's implant with a head 56 that abuts an incision through which the implant is inserted to stabilize the implant would prevent the implant from being inserted within the myocardium with the proximal end (head 56) below the endocardium surface and would further prevent the endocardium from healing over the incision through which the implant is inserted to seal off the implant within the myocardium.

Thus, Applicants respectfully submit that claims 68, 79, 111, and 116 are not anticipated by Rosenman. Claims 69-73, 75-78, 80-82, 112-115, and 121-128 depend from claims 68, 79, 111, and 116 and, likewise, are not anticipated by Rosenman. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants further recite, in independent claim 129, an implantable ocular drug delivery device comprising a coil-shaped body member that is implanted within a patient to deliver a drug substance to the patient via the body member, and a cap element that is in contact with the coil-shaped body member.

Applicants respectfully submit that Rosenman at least does not teach or suggest an ocular drug delivery device comprising a coil-shaped body member and a cap element that is in contact with the coil-shaped body member.

As shown in, for example, Figs. 18 and 19 of Rosenman, the coil-shaped portion 12 is connected to a head 56 via a linear segment and, thus, the head 56 is not in contact with the coil-shaped portion 12. Further, as set forth above, Rosenman's head 56 is not a cap within the meaning of Applicants' claims.

Accordingly, claim 129 is patentable over Rosenman.

Applicants further recite, in independent claim 83, a method for treating a patient comprising (a) providing a delivery device comprising a non-linear shaped body member having at least two deviations from a linear path and that has a shape other than a substantially C-configuration, the body member having a proximal end and a distal end, and a cap element at the proximal end, (b) inserting into a patient the device whereby the body member resides in the patient and the cap element abuts an incision through which the device is inserted to stabilize the device, and (c) allowing a therapeutic substance to be administered to the patient via the body member.

New claim 93 is similar, and recites a method for treating a patient comprising: (a) providing a delivery device comprising a coil-shaped body member; and (b) inserting into a patient eye the device whereby the coil-shaped body member is placed in the patient eye and a substance is delivered to the patient.

New claim 100 is similar, and recites method for treating a patient comprising: (a) providing a delivery device comprising a non-linear shaped body member having at least two deviations from a linear path and that has a shape other than a substantially C-configuration; and (b) inserting into a patient eye the device whereby the body member resides in the patient eye and a substance is administered to the patient.

As set forth above, Rosenman describes catheter systems for delivering drug delivery structures into the myocardium. Rosenman's drug delivery structure is implanted within the myocardium so that the proximal tip of the structure is at a depth below the endocardial surface (i.e. the structure is completely embedded within the myocardial tissue) to allow the endocardium to heal over the track wound created by inserting the device into the tissue such that, eventually, the healing response within the myocardium will seal the drug delivery structure off from the circulating blood within the heart chamber (See e.g. col. 10, line 62-col. 11, line 9; col. 14, line 62-col. 15, line 8).

Rosenman does not teach or suggest an implantable drug delivery device comprising a body member that is implanted within a patient during use and a cap element that abuts an incision through which the device is inserted to stabilize the device once implanted. Further, Rosenman does not teach or suggest or an implantable ocular drug delivery device comprising a body member that is implanted within a patient eye during use and a cap element that mates against the patient eye outer surface while the body member is inserted to the eye.

While Rosenman shows and describes in Figs. 18-19 a drug delivery helix having a head, the head is designed as a mechanism by which the delivery helix can be grasped by a delivery catheter. The head is not provided or designed as a cap capable of mating against a patient eye outer surface while the body member is inserted into the eye or capable of abutting an incision through which the device is inserted to stabilize the device once implanted.

As such, Rosenman does not teach or suggest a method for treating a patient by inserting into a patient a delivery device comprising a non-linear shaped body and a cap element at the

proximal end, whereby the body member resides in the patient and the cap element abuts an incision through which the device is inserted to stabilize the device (claim 83). As set forth, Rosenman requires that the delivery structure is completely embedded in the tissue such that the insertion wound will heal over to seal the drug delivery structure off.

Further, Rosenman does not teach or suggest a method for treating a patient by inserting a delivery device comprising a coil-shaped body member into a patient eye the device whereby the coil-shaped body member is placed in the patient eye and a substance is delivered to the patient (claim 93). Rosenman is directed towards devices and methods for implantation within the myocardium and other tissues. Rosenman is not at all designed or suitable for use in the vitreous of the eye, which presents very different requirements than insertion within tissues. For example, according to Rosenman, the drug delivery structure is implanted within the myocardium such that it is completely embedded within the myocardial tissue. This type of insertion method would not be suitable for implantation within the vitreous of the eye.

Further, Rosenman does not teach or suggest a method for treating a patient by inserting into a patient eye a delivery device comprising a non-linear shaped body member having at least two deviations from a linear path and that has a shape other than a substantially C-configuration, whereby the body member resides in the patient eye and a substance is administered to the patient (claim 100). As set forth above, Rosenman is directed towards devices and methods for implantation within the myocardium and other tissues. Rosenman is not at all designed or suitable for use in the vitreous of the eye, which presents very different requirements than insertion within tissues. For example, according to Rosenman, the drug delivery structure is implanted within the myocardium such that it is completely embedded within the myocardial tissue. This type of insertion method would not be suitable for implantation within the vitreous of the eye.

Accordingly, claims 83, 93, and 100 are patentable over Rosenman. Claims 84-92, 94-99, 101-110, and 117-120 depend from claims 83, 93, and 100 and, likewise, are patentable over Rosenman. Reconsideration and withdrawal of the rejection is respectfully requested.

## 2. 35 U.S.C. §103 Rejections

Claim 92 is rejected under 35 U.S.C. §103(a) over Rosenman and U.S. Patent No. 5,972,027 to Johnson (hereinafter “Johnson”). Applicants respectfully traverse.

As set forth above, Rosenman at least does not teach or suggest an implantable drug delivery device comprising a body member that is implanted within a patient during use and a cap element that abuts an incision through which the device is inserted to stabilize the device once implanted (independent claims 68 and 79) or an implantable ocular drug delivery device comprising a body member that is implanted within a patient eye during use and a cap element that mates against the patient eye outer surface while the body member is inserted to the eye (independent claims 111 and 116). As further set forth, Rosenman does not teach or suggest a method for treating a patient by inserting into a patient a delivery device comprising a non-linear shaped body and a cap element at the proximal end, whereby the body member resides in the patient and the cap element abuts an incision through which the device is inserted to stabilize the device (claim 83). As set forth, Rosenman requires that the delivery structure is completely embedded in the tissue such that the insertion wound will heal over to seal the drug delivery structure off.

Further, Rosenman does not teach or suggest a method for treating a patient by inserting into a patient a delivery device comprising a non-linear shaped body and a cap element at the proximal end, whereby the body member resides in the patient and the cap element abuts an incision through which the device is inserted to stabilize the device (claim 83), a method for treating a patient by inserting a delivery device comprising a coil-shaped body member into a patient eye the device whereby the coil-shaped body member is placed in the patient eye and a substance is delivered to the patient (claim 93), or a method for treating a patient by inserting into a patient eye a delivery device comprising a non-linear shaped body member having at least two deviations from a linear path and that has a shape other than a substantially C-configuration, whereby the body member resides in the patient eye and a substance is administered to the patient (claim 100).



Johnson describes porous stents for maintaining the patency of body passages. However, Johnson does not remedy the above-noted deficiencies in Rosenman.

Accordingly, claims 68, 79, 111, and 116 are patentable over Rosenman and Johnson. Claims 69-73, 75-78, 80-82, 112-115, and 121-128 depend from claims 68, 79, 111, and 116 and, likewise, are patentable over Rosenman and Johnson. Reconsideration and withdrawal of the rejection is respectfully requested.

### CONCLUSION

It is believed that the application is in condition for immediate allowance, and Applicants respectfully request early favorable action by the Examiner.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

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